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Report Highlights:

Taiwan authorities continue to strengthen a fairly rational regulatory environment for biotechnology. Taiwan's revised assessment guidelines for biotech crops are expected to take effect in 2008, and recently started implementing registration for stacked events. Taiwan is currently drafting its regulations to cover food derived from recombinant-DNA microorganisms and animals. Taiwan is also considering how to modify its regulatory system to address low level presence, nutritionally enhanced plants, and cloned animals. Unfortunately, prospects for commercializing a locally developed event have been reduced by the lack of political direction and a tendency to conduct research without thinking about the commercialization process.

Includes PSD Changes: No
Includes Trade Matrix: No
Annual Report
Taipei [TW1]
[TW]

I. Executive Summary

Taiwan has adopted a fairly rational regulatory environment for imported products. Product reviews for corn and soybean events are relatively smooth, but no food safety assessments have been completed for a locally developed biotech products. Nine events have been approved for conducting field testing, trials continue on seven, and a ring spot resistant papaya has conditionally passed field trials. Rules controlling the cultivation of biotech crops are still under development.

Taiwan is the U.S.'s sixth largest agricultural export market. In 2007, the United States exported more than \$3.3 billion of agricultural, fish and forest products to Taiwan, of which biotech products worth over \$1.5 billion. U.S. soybean exports totaled \$758 million, while corn exports were valued at \$713 million. Taiwan is the third largest export market for U.S. corn and for U.S. soybeans.

At the present time, Taiwan only regulates corn and soybeans and their products derived from recombinant-DNA. According to Taiwan's current biotech regulations, prior market approval for biotech soybean and corn imports is required for food, feed or processing use (FFP use). Biotech food labeling for certain corn and soy products and approval of all corn and soy events became mandatory on January 1, 2003. Labeling tolerance level is 5%. Non-GM labeling is on a voluntary basis. Import approval is also required for all biotech plants (LMOs) for environmental release or cultivation.

Taiwan's Department of Health (DOH) is the lead agency in granting approval to biotech products intended for food use while the Council of Agriculture (COA) regulates events intended for agricultural use. COA also regulates the field testing and environmental releases of new biotech products.

Taiwan has revised its Guidelines for Food Safety Assessment of Foods Derived from Recombinant-DNA Plants. Taiwan notified its proposed revisions to the WTO last November and received comments from interested members and industries. The final revised guidelines are anticipated to take effect this year. On May 6, Taiwan started implementing registration for stacked events. Taiwan is currently drafting regulations to cover food derived from recombinant-DNA microorganisms and animals. Taiwan is also looking into issues related to low level presence, nutritional enhanced plants, and cloned animals. It is possible that Taiwan is defining low level presence differently than the U.S.

II. Biotechnology Trade and Production

Production

Taiwan's commercialization policy may switch to focus on biotechnology export, but Taiwan researchers will face the same difficulties in commercializing crops in other markets that they face in Taiwan. In spite of several promising events in laboratories and in field trials, Taiwan has yet to legally commercialize a biotech crop. Some of the reasons for this are political, and others are purely practical. The researchers in Taiwan academic institutions have no experience putting an event through a regulatory process. Regulations for controlling the cultivation of biotech crops are still under development. Early drafts focus on liability and redress to the point of making even commercial seed production doubtful.

Reportedly, a ring spot resistance biotech papaya, which conditionally completed its field-testing in July 2003, has leaked out to commercial orchards from the developer's laboratory. Taiwan has found biotech papaya in the market places from its biotech food market surveillance inspection results. COA has clarified its biotech production position that growing

and/or marketing the unapproved biotech papaya on Taiwan is a violation of the Plant Variety and Plant Seeds Act to the farm community and that violators will be fined one to five million New Taiwan Dollars (NTD). COA has also established biotech papaya screening testing points at nursery farms. While biotech papaya was supposedly removed from the market after COA implemented these measures, biotech papaya may still be in commercial market channels. The Taiwan biotech papaya is also apparently widely cultivated in the Chinese Province of Hainan.

Taiwan produced papaya has been allowed to entry the Japan market since February 2005. Taiwan exported 36 tons of papaya, valued at \$172,000 to Japan in 2006. Despite the tiny papaya trade to Japan, Taiwan government has been extremely careful about its biotech papaya commercialization as Japan has been the largest export market for Taiwan agricultural products and biotech engineered papaya has yet to be allowed entry into Japan.

Development

There are no biotechnology crops under development on Taiwan that are expected to be on the market in the next two years. However, several rice, fruit and vegetable varieties are in field trails. In addition to crop events, several pharmaceutical applications on biotech animals are in field trails. Taiwan has established public field trails facilities at Council of Agriculture (COA) affiliated research institutes, while infrastructure for fishery trials is under construction. COA celebrated the grand opening of its biotech plant field trial facilities at the Taiwan Agriculture Research Institute (TARI) located in central Taiwan in late April 2007.

Imports

Taiwan is the U.S.'s sixth largest agricultural export market. In 2007, the United States exported more than \$3.3 billion of agricultural, fish and forest products to Taiwan. Included in that amount are soybean and corn biotech products worth over \$1.5 billion. U.S. soybean exports totaled \$758 million, while corn exports were valued at \$713 million. Taiwan is the third largest export market for U.S. corn and for U.S. soybeans. (These amounts do not include the \$140 million of U.S. cotton and cotton product exports to Taiwan.)

Taiwan's current biotech regulation require prior market approval for biotech soybeans and corn imports for food, feed or processing use (FFP use). Import approval is required for all biotech plants for environmental release or cultivation.

Food Aid

Taiwan is not a food aid recipient nor is it likely to be one in the near future.

Production of Non-U.S. Approved Varieties

Taiwan does not produce commercial quantities of biotechnology crops that were developed outside of the United States but have not passed through the U.S. regulatory system. The possible exception is the papaya which is an anti-viral event similar to the U.S biotech papaya. Taiwan is field-testing varieties that have not passed through the U.S. regulatory system.

III. Biotechnology Policy

Regulatory Framework

The proposed Biotech Basic Law is not currently being considered, and Taiwan is moving toward a U.S. style interagency approach. DOH is responsible for food safety risk assessment while the Council of Agriculture (COA) has oversight on events to be used in livestock and crop production or aquaculture. COA is also responsible for the environmental risk assessment for new events. The Bureau of Standards, Metrology, and Inspection (BSMI)

under the Ministry of Economic Affairs is responsible for import inspection. BSMI currently assists DOH in monitoring grain and oilseed shipments for the presence of biotech events. BSMI takes samples at the ports of entry for DOH's subsidiary agency, the Bureau of Food and Drug Analysis (BFDA) to conduct monitory import inspections on biotech soybean and corn events. BFDA also conducts market surveillance testing for all biotech food products, not limited to corn and soybeans and compliment of biotech labeling regulation. The National Science Council (NSC) supervises safety laboratory works in biotechnology. The top authority of Taiwan biotechnology regulatory system is held by an appointed minister without portfolio, the convener of the advisory committee for biotech products special task force and the Science and Technology Advisory Group (STAG) under Executive Yuan serves as Secretariat to the interagency advisory biotech products special task force.

The announcement of the draft revision of biotech food safety evaluation guidelines is scheduled in the second half of 2008, and guidelines on stacked traits were implemented in May 2008. Early reports are that the revised guidelines are similar to codex. The new draft guideline on stacked events approval is similar to those implemented in Mexico and Japan. If there is no interaction between the stacked events, and the events have already been approved, additional reviews will not be required. Taiwan is currently drafting its regulations to cover food derived from recombinant-DNA microorganisms and animals. Taiwan is also looking into issues related to low level presence, nutritional enhanced plants and cloned animals and plans to establish its regulatory system to address these hot issues.

DOH has also funded a Consultative Center for local crop developers to go to for help in going through the food safety regulatory process. DOH is also establishing laboratories to facilitate the food safety evaluation of locally developed biotech products.

The current Taiwan agricultural biotechnology regulations are only applied to soybeans, corn and products of soybean and corn. No bioengineered soybeans or corn may be produced, processed, prepared, packed, and imported or exported unless they are registered and approved by DOH Food Safety Bureau (FSB). Taiwan has approved 17 of the most widely commercialized bioengineered corn and soybean events. See appendix table for a list of these 17 biotech varieties as of May 6, 2008. For update list please contact the Post or DOH/BFS at:

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Taiwan implemented regulations for LMOs under the terms of its amended Plant Variety and Plant Seed Act, which went into effect June 9, 2005. Its related regulations and rulings can be found at:

<http://law.moj.gov.tw/eng/fnews/Fnmore.asp?lawType=c>. (This web link is built for browsing entire Taiwan regulations or regulatory environment; it is not limited to agricultural biotechnology.)

The "Rules for Approving Import/Export Transgenic Plants" were announced on July 7, 2005. Commodities for food, feed and processing use have been excluded from the ruling and are not required to apply for additional approval registration to the Taiwan authority at the Bureau of Animal and Plant Health Inspection and Quarantine (BAPHIQ). The web link is at:

<http://www.baphiq.gov.tw/ct.asp?xItem=9693&ctNode=1811&mp=1> (only Chinese version is available online. See appendix of the TW7036 for English translation...)

Biotech Food Approval Process

To gain DOH food safety approval, a biotech event must be reviewed by the Genetically Modified Food Safety Advisory Committee (GMFSAC), which is composed of 16 outside experts who evaluate the dossier. The committee is drawn mostly from the medical and academic communities. About one half of the current committee members served on the previous committee. The two-year term of the current committee began January 2008. The committee has become more efficient in terms of number of events granted approvals compared to earlier committees (see the list of approval events as of May 6, 2008). This is partly because many committee members have built up biotech food safety assessment experience in the fields of food toxicity and allergenicity, which are the focus of most concern.

On the other hand, DOH is adopting Codex standards and is revising its Guidelines for Food Safety Assessment. DOH has also contracted out two research projects on biotech papaya to generate food safety assessment regulatory data to assist researchers in regulatory approval dossier preparation.

Approvals

Below is a list of all biotech products approved on Taiwan for food, feed and processing (FFP). No product has been approved for environmental release (planting). Although COA has not yet amended its feed control act to adopt food or feed ingredients derived with biotechnology, it is likely to follow a policy of approving products for food and feed use after the Starlink incident. As a practical matter, and unofficially, DOH currently approves biotech events for both food and feed use.

Table 1: Taiwan Approved Biotech Products

Current Approvals of Genetically Modified Foods in Taiwan							
Update: 6 May 2008							
	UNIQUE IDENTIFIER	PRODUCT	NAME	EVENT	APPLICANT	DATE OF APPROVAL	NOTE
1	MON-Ø4Ø32-6	Soybean	Glyphosate tolerant Roundup Ready Soybean	40-3-2 (RRS)	Monsanto Far East Ltd., Taiwan Branch	July 22, 2002	Expiration: July 22, 2012
2	MON-ØØ81Ø-6	Corn	Insect-resistant YieldGard Corn	MON810	Monsanto Far East Ltd., Taiwan Branch	October 15, 2002	Expiration: October 15, 2012
3	MON-ØØØ21-9	Corn	Glyphosate tolerant Roundup Ready Corn	GA21	Monsanto Far East Ltd., Taiwan Branch	July 22, 2003	Expiration: July 22, 2008
4	MON-ØØ6Ø3-6	Corn	Glyphosate tolerant Roundup Ready Corn	NK603	Monsanto Far East Ltd., Taiwan Branch	April 11, 2003	Expiration: April 11, 2013
5	SYN-BTØ11-1	Corn	Insect-resistant & Glufosinate tolerant Corn	Bt11	Syngenta Taiwan Ltd.	June 2, 2004	Expiration: June 2, 2013
6	SYN-EV176-9	Corn	Insect-resistant & Glufosinate tolerant Corn	Event176	Syngenta Taiwan Ltd.	June 2, 2004	Expiration: June 2, 2013

7	ACS-ZM003-2	Corn	Glufosinate tolerant Corn	T25	Bayer CropScience	August 16, 2002	Expiration: August 16, 2012
8	DAS-01507-1	Corn	Insect-resistant & Glufosinate tolerant Corn	TC1507	DuPont Taiwan	November 17, 2003	Expiration: Nov. 17, 2008
9	DKB-89614-9	Corn	Insect-resistant & Glufosinate tolerant Corn	DBT418	Monsanto Far East Ltd., Taiwan Branch	October 16, 2003	Expiration: October 16, 2008
10	DKB-89790-5	Corn	Glufosinate tolerant Corn	DLL25	Monsanto Far East Ltd., Taiwan Branch	October 20, 2003	Expiration: October 20, 2008
11	MON-00863-5	Corn	Insect-resistant, YieldGard Rootworm Corn	MON863	Monsanto Far East Ltd., Taiwan Branch	October 16, 2003	Expiration: October 16, 2008
12	DAS-59122-7	Corn	Insect-resistant & Glufosinate tolerant Corn	59122	DuPont Taiwan	December 21, 2005	Expiration: December 21, 2010
13	MON-88017-3	Corn	YieldGard Rootworm/ Roundup Ready Corn	MON88017	Monsanto Far East Ltd., Taiwan Branch	March 20, 2006	Expiration: March 20, 2011
14	REN-00038-3	Corn	Lysine Maize	LY038	Monsanto Far East Ltd., Taiwan Branch	November 20, 2006	Expiration: November 20, 2011
15	ACS-GM005-3	Soybean	Glufosinate tolerant Soybean	A2704-12	Bayer CropScience	May 1, 2007	Expiration: May 1, 2012
16	SYN-IR604-5	Corn	Insect-resistant Corn	MIR604	Syngenta Taiwan Ltd.	October 22, 2007	Expiration: October 22, 2012
17	MON-89788-1	Soybean	Roundup RReady2Yield Soybean	MON89788	Monsanto Far East Ltd., Taiwan Branch	December 28, 2007	Expiration: December 28, 2012

Note: Taiwan event approvals last for five years. These products are approved only for FFP and not for planting.

Field Testing

In 1998 COA approved guidelines for field-testing of new crop and livestock events. More detailed regulations were published in November 2002, "Regulation for the Field Trial of Transgenic Breeding Livestock (Fowl) and the Bio-Safety Assessment," and June 2005, "The Administrative Regulations for the Field Testing of the Transgenic Plants". Field-testing regulations for aquaculture are still pending. However, the December 2002 edition of the Fisheries Act, Article 69, states that all transgenic fish shall be approved and have completed field-testing prior to commercialization.

On April 21, 2004, Taiwan amended its Plant Variety and Plant Seed Act by adding a new regulation for bioengineered seeds. Imported planting seed varieties are required to pre-register and approve with the Council of Agriculture (COA). Enforcement rules were available and effective on July 7, 2005. biotech planting seeds for exportation shall be also compliant to the enforcement rules.

Biotech Plants

Nine events were granted approval for running field testing for biosafety assessment, and their testing results are as follows. Two events completed field testing, one conditionally passed and the other didn't pass biosafety assessment. In July 2003, Taiwan conditionally approved a biotech ring spot virus resistant papaya. In June 2006, Taiwan disapproved one phytase rice variety developed by a private company, GeneTaiwan Co.

Seven events currently undergoing field testing for biosafety assessment.

1. Sweet rice for processing developed by Academia Sinica
2. Latoferri rice developed by National Chung Hsing University
3. Delay ripening broccoli developed by Academia Sinica
4. Phytase potato developed by Academia Sinica
5. Cucumber mottle mosaic virus resistance tomato developed by Asia Vegetable Research Development Center (AVRDC)
6. Eucalyptus for pulping developed by COA affiliate Taiwan Forestry Research Institute
7. New developed ring spot and leaf distortion mosaic virus resistance papaya

The developer of an Ornamented calla lily event has also applied for field-testing.

Biotech Animals

Gene cloned and transgenic pigs, cows and goats for biopharmaceutical uses have been or are being developed, but none of them have undergone field-testing. Taiwan has built a field testing center at the Animal Technology Institute Taiwan (ATIT), a non-profit governmental supported body, for transgenic pig, cow, chicken and goat field testing. The center has also established Standard Operation Practices (SOP) for field-testing. Now it awaits COA's accreditation for operating field testing.

Biotech Fish

Taiwan is about to break the ground to build a field testing center for transgenic fish. Taiwan's transgenic fish research is focus on ornamented fish, fluorescent fish in particular.

Stacked Events

On May 6, 2008, Taiwan implemented stacked event registration (See TW8025). All soybean and corn stacked events are now required to register for approval. The Guideline for Food Safety Assessment of Food Derived from biotech plants with Stacked Traits is regarded as a supplementary guideline for the existing Guideline for generic biotech plants. Therefore, Taiwan decided not to submit its WTO/SPS notification and did not set a registration approval deadline, either. The language in the stacked event guideline also states that the guideline will undergo constant revision to adopt emerging technology and international guidelines. However, Taiwan's lack of WTO notification has created a concern over non-transparency.

Non-Biotech Coexistence

While Taiwan does not yet have a policy on coexistence between biotechnology and non-biotechnology crops, interest is rising. As Taiwan doesn't have its coexistence policy, no biotech crop will be released for planting at the present time. Two of the chief problems are

an unrealistic demand from some quarters for no gene flow and a tendency to emphasize redress and liability.

Labeling

Taiwan's bioengineered food safety approval and labeling regulation took effect on January 1, 2003. Mandatory labeling of bioengineered food was phased in over a two to four year period. Beginning in January 2005, all food made of biotech soybean or corn is required to label. The tolerance level is 5 percent.

The labeling regulations do not apply to products that do not contain pieces of transgene(s) or protein such cornstarch, corn syrup, corn oil, sugar, soy oil, and soy sauce. However, labeling may be introduced for food made of non soy and corn ingredients in the future.

On all biotech food labels, the Chinese character size should not be smaller than 2x2 mm. The label should be put adjacent to soybean or corn in the finished products ingredients list or in other easily visible place on the package. There is no standard required format. Note: Soybean or corn food products that are not packaged for retail sale are not subject to the biotech food labeling requirement – this includes the large volume of products sold in wet markets and restaurants. Soybean and corn food products made of non-GM materials can be voluntarily labeled Non-GM or Not-GM. The implementation date for voluntary Non-GM food labeling was January 1, 2001. If there is no biotech alternative available, a product may not be labeled "Non-GM". DOH has actually forced the re-labeling of such products as "Non-GMO Coffee."

According a market surveillance inspection result conducted by DOH annually, about 95 percent of food on the market was compliance Taiwan biotech food labeling regulation.

Biosafety Protocol

Taiwan cannot sign the Cartagena Protocol on Biosafety (CPB) because it is not internationally recognized as a sovereign state. However, in the past, Taiwan has unilaterally implemented some international agreements and is expected to incorporate Cartagena guidelines into its import-export regulation governing biotech products for seeds and planting (see appendix). COA's Bureau of Animal and Plant Inspection and Quarantine (BAPHIQ) is the lead agency on the issue.

Trade Barriers Unlikely

Despite incidences of commingled biotech events of StraLink corn, LibertyLink Rice and Event 32 corn, there have been no trade disruptions of U.S. biotech product exports.

Taiwan's approval process has become increasingly efficient since the third GMFSE Committee is formed and acting in January 2007. The Genetically Modified Food Safety Advisory Committee (GMFSAC) meetings are delayed some times because members are academics with heavy outside commitments such as giving lectures and grading exams. But the committee has mostly overcome the meeting schedule problem and has enhanced communications among committee members, government and industry.

Taiwan's inability to commercialize locally developed products such as biotech rice and vegetables are due to several factors. There is a lack of political direction which results in risk adverse behavior by government officials. There is a lack of experience in putting together regulatory submissions and conducting the necessary tests. Perhaps most importantly the research approach is often academic. Crop developers often do not begin the development process with commercialization as the objective or have a plan for commercialization. DOH/FSB has contracted out two projects for 2008-2009 to develop the food safety regulatory submission for the second generation biotech papaya.

Pending Legislation

The current Taiwan regulatory system for biotechnology is similar to the U.S. interagency system. DOH/FSB is the lead agency for food safety, COA for environmental safety and NSC for research.

The Executive Yuan (Cabinet) is currently reviewing an interagency-proposed comprehensive biotech basic law covering agricultural and pharmaceutical biotechnology development. The law may also cover areas such as intellectual property rights, the biosafety protocol, as well as food and environmental safety. The law will serve as regulatory framework for all regulations that govern biotechnology. The disparity of opinion on the issue has made creating a workable draft law very difficult, and a final version has not been drafted.

IV. Marketing**Consumers**

Taiwan consumers are actually consuming biotech soy products, tofu and soy milk, on a daily basis.

With exception of organic food consumers who are generally skeptical about biotech foods, most consumers are not aware of biotech food. In general, they continue to purchase food in bulk from traditional wet markets and eat traditional Chinese breakfasts with soymilk made with biotech soybeans. Despite this, consumption of processed non-biotech food such as soymilk and tofu is gradually increasing because local food companies use non-GM promotion as a marketing tool to create image that non-GM is better or value food.

Producers/Importers

Current labeling regulations have led some food processors to promote foods made with non-biotech corn or soybeans. Food processors that make products in bulk without labeling generally ignore the existence of biotechnology and emphasize their traditional business. Some local wheat millers have warned that they will reject biotech wheat, but Taiwan feed millers – who import corn for animal feed – mostly pay attention to trade issues such as biotech product approvals and/or prevention of import disruptions.

Retailers

Except specialty organic food retailing, most of retailing stores stay neutral and provide diversity brands or types food products, both non-biotech and biotech. As of reporting date, there is no country specific study on the marketing on biotech food available.

V. Capacity Building and Outreach

Taiwan's substantial agricultural research infrastructure, sound legal system, favorable climate and very strong information technology base have been contributed to its ability to develop a world-class biotech sector. In addition, a science-based regulatory system and relative lack of anti-biotech protectionist interests has given the public confidence in the safety of biotech foods.

The primary focus is to build upon these strengths by enhancing Taiwan's regulatory capacity and to explain the benefits of biotechnology to the public. AIT has focused heavily on regulatory cooperation, creating linkages between the biotech sectors on Taiwan and in the United States and working with the media.

Past Activities

AIT Taipei has been actively engaged in a series of U.S. Government and USDA-funded capacity building and outreach activities related to agricultural biotechnology. In reverse chronological order, major activities include:

May 2008: USGC lead a delegation composed of three committee members of GMFSAC visiting the United States communicating to Washington and industry representatives on newly implemented stacked traits registration.

October 2007: DOH contracted out to the Food Industry Research Institute (FIRDI) a biotech outreach program. A seminar on biotech food safety was held after the 7th session of the Ad Hoc Intergovernmental Task Force on Foods Derived from Biotechnology in Chiba, Japan. Low level Presence (LLP) discussion in the 7th session of the Task Force was included at the seminar.

September 2007 & 2008: AIT, National Taiwan University, and the Council of Agriculture, and several regional agriculture institutions cosponsored a biotechnology training course for government officials and regulators from across Southeast Asia. The same program will be launched second in 2008.

In addition to AIT-led efforts, the U.S. Grain Council, American Soybean Association offices and CropLife Asia have very active biotech programs on Taiwan.

USGC continued supporting local media reporters attending Bio Conference held in the United States in the spring and supporting Taiwan officials attending its International Agricultural Biotechnology Information Conference in the fall each year to facilitate biotechnology communication.

In addition to seminars, there will be workshops on environmental and food safety assessment and a communication program for media and academia as budget is available.

VI. Reference

Useful Websites

<http://law.moj.gov.tw>
<http://www.doh.gov.tw>
<http://www.coa.gov.tw>